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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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022932
IMMUNEX CORPORATION
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HM12/0221

EXAMINER

ART UNIT	PAPER NUMBER
1644	5

DATE MAILED: 02/21/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-14 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☑ Claim(s) 1-14 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7 and 14, drawn to a method of augmenting an immune response with flt3-ligand and a CD40 binding protein, 4-1BB, 4-1BB-specific antibodies, interferon alpha, RANKL and CD30L antagonists; classified in Class 424, subclass 85.1 and 130.1.

II. Claims 8-9, drawn to dendritic cell preparations; classified in Class 435, subclass 2.

III. Claims 11-12, drawn to antigen-expressing dendritic cells; classified in Class 435, subclass 325 and 455.

IV. Claims 10 and 13, drawn to a method of preparing antigen-presenting dendritic cells, classified in Class 435, subclass 375 and 455.

It is noted that claims 13 is dependent upon claim 12, but it appears that claim 13 should be dependent on claim 10 instead.

3. Inventions I and IV are different methods, which require different ingredients, process steps and endpoints. Therefore, they are patentably distinct.

4. Inventions II and III are different products. Dendritic cells and antigen presenting dendritic cells differ in structure given the additional element(s) of an antigen, which require non-coextensive searches. Therefore, they are patentably distinct.

5. Inventions IV and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the antigen presenting dendritic cells can be made by various immunological and recombinant procedures which do not require flt3-ligand and do not require stem or progenitor cell populations as the starting biological materials.

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IV is not required for any other group from Groups I-IV and Groups I-IV have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed Groups I-IV: wherein the compound in addition to flt3-ligand is:

A) 4-1BB,
B) 4-1BB-specific antibody,
C) CD40 binding protein as it reads on CD40 ligand or
D) CD40 binding protein as it reads on CD40-specific antibodies,
E) interferon alpha,
F) RANKL,
G) CD30L-specific antibodies, or
H) soluble CD30-Fc fusion polypeptides.

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 8, 10 and 12 are generic.

8. In addition to electing a species from Section 7 above, applicant is required to elect a further species of molecules/cytokines selected from the following. This application contains claims directed to the following patentably distinct species of the claimed Groups I-IV: wherein the molecule/cytokine in addition to flt3-ligand and A-E above in section 7 is:

A) GM-CSF,
B) IL-4,
C) TNF-α,
D) IL-3,
E) c-kit ligand, or
F) fusions or GM-CSF and IL-3.

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 8, 10 and 12 are generic.

9. This application contains claims directed to the following patentably distinct species of the claimed Group I wherein the augmentation of the immune response is drawn to

A) a patient having cancer,
B) a patient having an infectious disease, or
C) enhancing the immune response to a vaccine antigen.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 is generic.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
February 20, 2001